# Exhibit 300: Capital Asset Plan and Business Case Summary

## Part I: Summary Information And Justification (All Capital Assets)

### Section A: Overview (All Capital Assets)

**1. Date of Submission:** 2010-03-17 14:09:06

**2. Agency:** 009

**3. Bureau:** 10

**4. Name of this Investment:** FDA Harmonized Inventory

**5. Unique Project (Investment) Identifier:** 009-10-01-03-01-0061-00

**6. What kind of investment will this be in FY 2011?:** Full-Acquisition

- Planning
- Full Acquisition
- Operations and Maintenance
- Mixed Life Cycle
- Multi-Agency Collaboration

**7. What was the first budget year this investment was submitted to OMB?** *

**8. Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap; this description may include links to relevant information which should include relevant GAO reports, and links to relevant findings of independent audits.**

The Harmonized Inventory (HI) database will provide an accurate and reliable inventory of FDA related entities with unique identifiers. FDA-related entities encompass firms, facilities, products, services, components/ingredients, and their points of contact. The HI project will allow for the building of integration relationships between entity information and other information such as product submissions, product approvals, clinical trials, inspections, import entries, sample analysis, recalls, complaints, adverse event reports and compliance actions. The integration of data sources will support FDA in its mission to ensure product quality, safety and compliance through access to complete and reliable information about FDA-related entities. HI will leverage the various legacy systems to form an accurate, reliable and sole authoritative source of FDA-related entity information. This harmonization of business processes will emphasize improved usability and productivity/efficiency for end users, as well as empowerment of users to perform work at required quality levels with greater consistency. This effort is expected to increase productivity and improve management of entity inventory information, leading to a single point of entry to retrieve and access accurate information. It will also enable effective and timely regulatory decision making. Due to the problems identified below, there are serious questions about the integrity of this data that Harmonized Inventory will begin to address: Inconsistent and unreliable information on facilities, outdated Data, firms are only required to report periodically (e.g., once or twice a year). Multiple Identifiers, inefficiency, lack of historical, inability to link FDA regulated products and combination products not adequately addressed. In addition, GAO released several reports over the past decade calling for FDA to increase its efficiency in protecting food safety by variously relying on other agencies, foreign governments, or the states to control food production, or use risk-based inspection methods, or exercise more effective control at the border, agencies, foreign governments, or the states to control food production or use risk-based inspection methodsor exercise more effective control at the border. All of these options would provide an easily used and accurate inventory.

a. **Provide here the date of any approved rebaselining within the past year, the date for the most recent (or planned)alternatives analysis for this investment, and whether this investment has a risk management plan and risk register.**

**9. Did the Agency's Executive/Investment Committee approve this request?** *

a. **If "yes," what was the date of this approval?** *

**10. Contact information of Program/Project Manager?**

- **Name:** *
- **Phone Number:** *
- **Email:** *

**11. What project management qualifications does the Project Manager have? (per FAC-P/PM)?** *

- Project manager has been validated according to FAC-PMPM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/OM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

**12. If this investment is a financial management system, then please fill out the following as reported in the most recent financial systems inventory (FMSI):**

| Financial management system name(s) | System acronym | Unique Project Identifier (UPI) number |
|---|---|---|
| * | * | * |

a. **If this investment is a financial management system AND the investment is part of the core financial system then select the primary FFMIA compliance area that this investment addresses (choose only one):** *

- computer system security requirement;
- internal control system requirement;
- core financial system requirement according to FSIO standards;
- Federal accounting standard;
- U.S. Government Standard General Ledger at the Transaction Level;
- this is a core financial system, but does not address a FFMIA compliance area;
- Not a core financial system; does not need to comply with FFMIA

**Section B: Summary of Funding (Budget Authority for Capital Assets)**

**1.**

**Table 1: SUMMARY OF FUNDING FOR PROJECT PHASES (REPORTED IN MILLIONS)**
**(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)**

| | PY1 and earlier | PY 2009 | CY 2010 | BY 2011 | BY+1 2012 | BY+2 2013 | BY+3 2014 | BY+4 and beyond | Total |
|---|---|---|---|---|---|---|---|---|---|
| Planning: | * | * | * | * | * | * | * | * | * |
| Acquisition: | * | * | * | * | * | * | * | * | * |
| Subtotal Planning & Acquisition: | * | * | * | * | * | * | * | * | * |
| Operations & Maintenance: | * | * | * | * | * | * | * | * | * |
| Disposition Costs (optional): | * | * | * | * | * | * | * | * | * |
| SUBTOTAL: | * | * | * | * | * | * | * | * | * |
| **Government FTE Costs should not be included in the amounts provided above.** | | | | | | | | | |
| Government FTE Costs | * | * | * | * | * | * | * | * | * |
| Number of FTE represented by Costs: | * | * | * | * | * | * | * | * | * |
| TOTAL(including FTE costs) | * | * | * | * | * | * | * | * | * |

**2. If the summary of funding has changed from the FY 2010 President's Budget request, briefly explain those changes:**

*

**Section C: Acquisition/Contract Strategy (All Capital Assets)**

**1.**

**Table 1: Contracts/Task Orders Table**

| Contract or Task Order Number | Type of Contract/Task Order (In accordance with FAR Part 16) | Has the contract been awarded (Y/N) | If so what is the date of the award? If not, what is the planned award date? | Start date of Contract/Task Order | End date of Contract/Task Order | Total Value of Contract/Task Order (M) | Is this an Interagency Acquisition? (Y/N) | Is it performance based? (Y/N) | Competitively awarded? (Y/N) | What, if any, alternative financing option is being used? (ESPC, UESC, EUL, N/A) | Is EVM in the contract? (Y/N) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| RFP# 09223SOL00185 | T&M: Time & Materials | Y | 2009-09-15 | 2009-09-15 | 2010-09-14 | $2.0 | * | * | * | * | * |
| HHSF223200750663G | T&M: Time & Materials | Y | 2009-08-01 | 2009-08-01 | 2010-08-01 | $1.0 | * | * | * | * | * |
| Data Standards/Foods - HHSF2232009102230P | T&M: Time & Materials | Y | 2009-08-23 | 2009-08-24 | 2010-08-23 | $0.1 | * | * | * | * | * |
| Data Standards/Foods HHSF223200950194P | T&M: Time & Materials | Y | 2009-08-05 | 2009-08-31 | 2010-08-31 | $0.1 | * | * | * | * | * |
| Data Standards/Foods - IAG # 224073564 | C: Cost | Y | 2009-08-06 | 2009-08-06 | 2009-09-30 | $0.6 | * | * | * | * | * |
| National Library of Medicine (NLM) IAG# 224-09-8512 | C: Cost | Y | 2009-08-11 | 2009-08-25 | 2010-08-26 | $0.3 | * | * | * | * | * |
| HHSF223200950011C | T&M: Time & Materials | Y | 2009-09-15 | 2009-09-15 | 2010-09-15 | $2.0 | * | * | * | * | * |

**2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:**
*

**3. Is there an acquisition plan which reflects the requirements of FAR Subpart 7.1 and has been approved in accordance with agency requirements?** *

a. **If "yes," what is the date?** *

**Section D: Performance Information (All Capital Assets)**

**Table 1: Performance Information Table**

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|---|---|---|---|---|---|---|---|
| 2010 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase of otc drug registrations containing electronically-formatted labels and listing details associated with the database record | 0% | 50% | tbd |
| 2010 | Effective Management of Human Capital/Information Technology/Resources | * | * | % reduction in fda annual costs for manual data entry services to support drug registration and listing including contractor support | 0% | 50% | tbd |
| 2010 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase in drug firms and facilities filing electronic registrations | 20% | 75% | tbd |
| 2010 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase in drug firms and facilities filing electronic registrations | 20% | 80% | tbd |
| 2010 | Effective Management of Human Capital/Information Technology/Resources | * | * | reduction in number of days required for automated processing of registration and listing submissions/applications | 60 days | 5 days | tbd |
| 2010 | Effective Management of Human Capital/Information Technology/Resources | * | * | reduction in number of days required to acknowledge receipt of drug company submissions | 30 days | 1 days | tbd |
| 2010 | Effective Management of Human Capital/Information Technology/Resources | * | * | % percentage reduction in the discrepancy of external reporting of statistics related to foreign drug facilities importing products to the u.s. | 100% | 50% | tbd |
| 2010 | S.O. 2.2 - Protect the | * | * | % increase in the number of | 0% | 50% | tbd |

**Table 1: Performance Information Table**

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|---|---|---|---|---|---|---|---|
| | public against injuries and environmental threats | | | electronic registration and listing files for foods added to the database. | | | |
| 2011 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | inclusion of drug otc labels, registrations and listings in electronic format | 50% | 90% | tbd |
| 2011 | Effective Management of Human Capital/Information Technology/Resources | * | * | % reduction in fda annual costs for manual data entry services to support registration and listing including contractor support | 50% | 90% | tbd |
| 2011 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase in electronic registration of drug firms and facilities | 50% | 90% | tbd |
| 2011 | Effective Management of Human Capital/Information Technology/Resources | * | * | reduction in number of days required to process registration and listing | 5 days | 1 days | tbd |
| 2011 | Effective Management of Human Capital/Information Technology/Resources | * | * | % percentage reduction in the discrepancy of external reporting of statistics related to foreign drug facilities importing products to the u.s. | tbd | tbd | tbd |
| 2012 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase of otc drug registrations containing electronically-formatted labels and listing details associated with the database record | tbd | tbd | tbd |
| 2012 | Effective Management of Human Capital/Information Technology/Resources | * | * | % reduction in fda annual costs for manual data entry services to support drug registration and listing including contractor support | tbd | tbd | tbd |

**Table 1: Performance Information Table**

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|---|---|---|---|---|---|---|---|
| 2012 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase in drug firms and facilities filing electronic registrations | tbd | tbd | tbd |
| 2012 | Effective Management of Human Capital/Information Technology/Resources | * | * | reduction in number of days required for automated processing of registration and listing submissions/applications | tbd | tbd | tbd |
| 2012 | Effective Management of Human Capital/Information Technology/Resources | * | * | reduction in number of days required to acknowledge receipt of drug company submissions | tbd | tbd | tbd |
| 2012 | Effective Management of Human Capital/Information Technology/Resources | * | * | % percentage reduction in the discrepancy of external reporting of statistics related to foreign drug facilities importing products to the u.s. | tbd | tbd | tbd |
| 2012 | Effective Management of Human Capital/Information Technology/Resources | * | * | inclusion of drug otc labels, registrations and listings in electronic format | tbd | tbd | tbd |
| 2012 | Effective Management of Human Capital/Information Technology/Resources | * | * | % reduction in fda annual costs for manual data entry services to support registration and listing including contractor support | tbd | tbd | tbd |
| 2013 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase in electronic registration of drug firms and facilities | tbd | tbd | tbd |
| 2013 | Effective Management of Human Capital/Information Technology/Resources | * | * | reduction in number of days required to process registration and listing submissions/applications | tbd | tbd | tbd |
| 2013 | Effective | * | * | % percentage | tbd | tbd | tbd |

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|---|---|---|---|---|---|---|---|
| | Management of Human | | | reduction in the discrepancy of external reporting of statistics related to foreign drug facilities importing products to the u.s. | | | |
| 2013 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | inclusion of drug otc labels, registrations and listings in electronic format | tbd | tbd | tbd |
| 2014 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | reduction in fda annual costs for manual data entry services to support registration and listing including contractor support | tbd | tbd | tbd |
| 2014 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | inclusion of drug otc labels, registrations and listings in electronic format | tbd | tbd | tbd |
| 2014 | Effective Management of Human Capital/Information Technology/Resources | * | * | % reduction in fda annual costs for manual data entry services to support registration and listing including contractor support | tbd | tbd | tbd |
| 2014 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | % increase in electronic registration of drug firms and facilities | tbd | tbd | tbd |
| 2014 | Effective Management of Human Capital/Information Technology/Resources | * | * | reduction in number of days required to process registration and listing submissions/applications | tbd | tbd | tbd |
| 2014 | Effective Management of Human Capital/Information Technology/Resources | * | * | % percentage reduction in the discrepancy of external reporting of statistics related to foreign drug facilities importing products to the | tbd | tbd | tbd |

**Table 1: Performance Information Table**

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|---|---|---|---|---|---|---|---|

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# Part II: Planning, Acquisition And Performance Information

## Section A: Cost and Schedule Performance (All Capital Assets)

### 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
|---|---|---|---|---|---|---|---|---|
| FY '09, Phase1: HI Registration & Listing (a.k.a eLIST) preliminary planning, development of PRPLLR, business & IT PM support, design and development | $0.6 | $0.6 | 2008-09-01 | 2008-09-01 | 2009-08-30 | 2009-08-30 | 100.00% | 100.00% |
| FY '09, Phase 1: HI Regisitration & Listing: O & M (system maintenance) | $0.1 | $0.1 | 2009-02-01 | 2009-02-01 | 2010-02-01 | 2010-02-01 | 100.00% | 100.00% |
| FY '09, Phase 2 of HI for drugs: Initiation phase (boundary for all phases) | $0.2 | $0.2 | 2009-06-15 | 2009-06-15 | 2009-10-30 | 2009-10-07 | 100.00% | 100.00% |
| FY '09, Phase 2 of HI for drugs: Concept phase | $0.3 | $0.1 | 2009-06-15 | 2009-06-15 | 2009-11-30 | 2009-11-30 | 100.00% | 100.00% |
| FY '09, Phase 2 of HI for drugs: Planning phase | $2.0 | $0.3 | 2009-06-15 | 2009-06-15 | 2010-08-31 | | 93.00% | 93.00% |
| FY '09, Phase 2 of HI for drugs: Implementation (NLM) | $0.3 | $0.1 | 2009-08-25 | 2009-08-25 | 2010-08-26 | | 25.00% | 25.00% |
| FY '09, Phase 2 of HI for drugs: Planning (sub-project for D&B / FML) | $3.1 | $0.4 | 2009-09-15 | 2009-09-15 | 2010-09-21 | | 79.00% | 55.00% |
| FY '09, Phase 2 of HI for drugs and core HI: Requirements analysis phase | $2.0 | $0.1 | 2009-09-15 | 2009-09-17 | 2010-09-15 | | 39.00% | 85.00% |
| FY '10, Phase 2 of HI for | $1.5 | $0.0 | 2010-02-01 | 2010-02-01 | 2010-05-01 | | 40.00% | 40.00% |

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
|---|---|---|---|---|---|---|---|---|
| drugs: Design | | | | | | | | |
| FY '10, ICT21 | $0.6 | $0.0 | 2010-02-01 | 2010-02-01 | 2011-02-01 | | 20.00% | 0.00% |
| FY '10, Phase 2 of HI for drugs: Development phase | * | * | 2010-05-01 | | 2010-09-01 | | 0.00% | 0.00% |
| FY '10, Phase 2 of HI for drugs: Integration & testing phase | * | * | 2010-09-01 | | 2010-12-01 | | 0.00% | 0.00% |
| FY '10: Phase 2 of HI for drugs: Implementation (including training) | * | * | 2010-12-01 | | 2011-02-01 | | 0.00% | 0.00% |
| FY '10: Phase 2 of HI for drugs: Implementation (NLM) | * | * | 2010-08-27 | | 2011-08-27 | | 0.00% | 0.00% |
| FY '10: Phase 2 of HI for drugs: O & M | * | * | 2010-02-01 | | 2011-01-31 | | 0.08% | 0.08% |
| FY '10, Phase 3 Planning: (subproject for FML and D & B) | * | * | 2010-09-22 | | 2011-09-22 | | 0.00% | 0.00% |
| FY '10, Phase 3 Planning: (subproject for Data Standards for radition emitting devices, imports,tissue. and blood and cosmetics | * | * | 2010-09-01 | | 2011-09-01 | | 0.00% | 0.00% |
| FY '10, Phase 3 of HI for foods: planning | * | * | 2010-08-02 | | 2011-08-02 | | 0.00% | 0.00% |
| FY '10, Phase 3 of HI for foods: requirements analysis | * | * | 2010-02-01 | | 2011-01-31 | | 0.08% | 0.08% |
| FY '10, Phase 3 of HI for foods: design | $2.0 | $2.0 | 2010-01-01 | 2010-01-01 | 2010-04-01 | 2010-04-01 | 100.00% | 100.00% |
| FY '10, Phase 3 of HI for foods: development | * | * | 2010-04-01 | | 2010-08-01 | | 0.08% | 0.08% |
| FY '11, Phase 3 of HI for | * | * | 2010-08-01 | | 2010-11-01 | | 0.00% | 0.00% |

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
|---|---|---|---|---|---|---|---|---|
| foods: Integration & testing phase | | | | | | | | |
| FY '11, Phase 3 of HI for foods: Implementation (including training) | * | * | 2010-11-01 | | 2011-01-01 | | 0.00% | 0.00% |
| FY '11: Phase 3 of HI for foods: O & M | * | * | 2011-02-01 | | 2012-02-01 | | 0.00% | 0.00% |
| FY '11, Phase 4 of HI for Tobacco and other: Requirements analysis phase (tobacco/non-related entities/other) | * | * | 2011-04-01 | | 2012-04-01 | | 0.00% | 0.00% |
| FY '11, Phase 4 of HI for Tobacco and other: Planning phase | * | * | 2010-09-30 | | 2011-09-30 | | 0.00% | 0.00% |
| FY '11, Phase 4 of HI for Tobacco and other: Planning phase | * | * | 2011-09-02 | | 2012-09-02 | | 0.00% | 0.00% |
| FY '11, Phase 4 Requirements for HI for Medical devices and other | * | * | 2010-10-01 | | 2011-10-01 | | 0.00% | 0.00% |
| FY '11, Phase 3 of HI for Design and Development for Foods | * | * | 2010-10-01 | | 2011-10-01 | | 0.00% | 0.00% |
| FY '11, Phase 4 of HI for Tobacco and other: Planning phase (subprojects: D&B and FML) | * | * | 2011-09-23 | | 2012-09-23 | | 0.00% | 0.00% |
| FY '11, Phase 4 of HI for MARCS Imports | * | * | 2011-09-15 | | 2012-09-15 | | 0.00% | 0.00% |

* - Indicates data is redacted.